IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY, and EDEN BIODESIGN, LLC,<br><br>Plaintiffs;<br><br>v.<br><br>AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., ALKEM LABORATORIES LTD., HETERO LABS LIMITED, HETERO USA INC., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, and ZYDUS PHARMACEUTICALS (USA) INC.,<br><br>Defendants. | Civil Action No. 19-cv-1727-RGA |

MEMORANDUM OPINION

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Jeffrey J. Lyons, BAKER & HOSTETLER, Wilmington, DE; Peter Armenio (argued), QUINN EMANUEL URQUHART & SULLIVAN, New York, NY; Amanda Antons (argued), QUINN EMANUEL URQUHART & SULLIVAN, Chicago, IL,
Attorneys for Plaintiffs.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, DE; George J. Barry, III, Timothy H. Kratz, KRATZ & BARRY LLP, Atlanta, GA,
Attorneys for Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

John C. Phillips, Jr., David A. Bilson, PHILLIPS, McLAUGHLIN & HALL, P.A., Wilmington, DE; Andrea L. Cheek, Andrew E. Morrell, Justin E. Culbertson, William R. Zimmerman, KNOBBE MARTENS OLSON & BEAR LLP, Washington, DC; Carol M. Pitzel Cruz (argued), KNOBBE MARTENS OLSON & BEAR LLP, Seattle, WA,
Attorneys for Defendant Alkem Laboratories Limited.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, DE; Dimitry V. Shelhoff (argued), Edward D. Pergament, Kenneth S. Canfield, PERGAMENT & CEPEDA LLP, Morristown, NJ,
Attorneys for Hetero Labs Limited and Hetero USA Inc.

Stamatios Stamoulis, STAMOULIS & WEINBLATT LLC, Wilmington, DE; Richard Juang, GOLDBERG SEGALLA LLP, St. Louis, MO,
Attorneys for Defendants MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc.

Dominick T. Gattuso, HEYMAN ENERIO GATTUSO & HIRZEL LLP, Wilmington, DE; Charles B. Klein (argued), Gregory J. Winter, Jovial Wong, Zachary B. Cohen, WINSTON & STRAWN LLP, Washington, DC,
Attorneys for Defendant Sun Pharmaceutical Industries Limited.

Pilar G. Kraman, Beth A. Swadley, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE; Carolyn A. Blessing, David B. Abramowitz, Emily L. Savas (argued), Jonathan B. Turpin, Michael J. Gaertner, LOCKE LORD LLP, Chicago, IL,
Attorneys for Defendant Zydus Pharmaceuticals (USA) Inc.

January 11, 2021

/s/ Richard G. Andrews
**ANDREWS, U.S. DISTRICT JUDGE:**

Before the Court is the issue of claim construction of various terms in U.S. Patent Nos. 8,691,860 ("the '860 patent"), 9,115,091 ("the '091 patent"), 9,364,489 ("the '489 patent"), 9,789,125 ("the '125 patent"), 9,675,587 ("the '587 patent"), and 10,188,632 ("the '632 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 129). The Court heard oral argument on December 21, 2020. (D.I. 136).

## I. BACKGROUND

This is a Hatch-Waxman action regarding Plaintiffs' VIBERZI® brand (eluxadoline) products for the treatment of irritable bowel syndrome with diarrhea. In this action, the asserted patents are directed to either (1) crystalline forms of eluxadoline and their use to treat certain disorders; or (2) abuse-deterrent formulations containing eluxadoline that minimize eluxadoline's potential to be abused. The Crystalline Form Patents are the '860 patent, the '091 patent, the '489 patent, and the '125 patent. The Abuse-Deterrent Patents are the '587 patent and the '632 patent.

The parties agreed on the constructions for sixteen claim terms and dispute the constructions of five claim terms in the asserted patents.

## II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*,

415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic

evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id*.

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

## III. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

| Claim Term | Construction |
|---|---|
| "A method of treating a mammal suffering from irritable bowel syndrome, pain or another opioid receptor disorder" ('860 Patent, Claim 9) | Preamble is limiting. |
| "A method of treating a disease in a mammal, wherein the disease is an opioid receptor disorder" ('091 Patent, Claim 15) | Preamble is limiting. |
| "A method of treating a mammal suffering from irritable bowel syndrome" ('489 Patent, Claim 1) | Preamble is limiting. |
| "A method of treating a mammal suffering from pain" ('489 Patent, Claim 9) | Preamble is limiting. |
| "A method of treating an opioid receptor disorder in a mammal" ('125 Patent, Claim 17) | Preamble is limiting. |
| "An abuse-deterrent, monophasic pharmaceutical composition suitable for single dose administration for treating a condition mediated by an opioid receptor" ('587 Patent, Claims 1, 5, and 7) | Preamble is limiting. |
| "A solid pharmaceutical dosage formulation" ('632 Patent, Claim 1) | Preamble is limiting. |
| "A pharmaceutical composition" ('632 Patent, Claims 14 and 15) | Preamble is limiting. |

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| "about 0.65%-0.85% by weight of colloidal silica" ('587 Patent, Claim 2; '632 Patent, Claim 8) | 0.60-0.90% by weight of colloidal silica |
| "about 0.65-0.85% by weight of magnesium stearate" ('587 Patent, Claim 2; '632 Patent, Claim 8) | 0.60-0.90% by weight of magnesium stearate |
| "about 0.75% by weight of colloidal silica" ('587 Patent, Claim 3; '632 Patent, Claim 9) | 0.70-0.80% by weight of colloidal silica |
| "about 0.75% by weight of magnesium stearate" ('587 Patent, Claim 3; '632 Patent, Claim 9) | 0.70-0.80% by weight of magnesium stearate |
| "about 4.5 mg of colloidal silica" **(**'587 Patent, Claim 5; '632 Patent, Claim 14) | 4.2-4.8 mg of colloidal silica |
| "about 4.5 mg by weight of magnesium stearate" ('587 Patent, Claim 5; '632 Patent, Claim 14) | 4.2-4.8 mg of magnesium stearate |
| "about 6 mg of colloidal silica" ('587 Patent, Claim 7; '632 Patent, Claim 15) | 5.5-6.4 mg of colloidal silica |
| "about 6 mg by weight of magnesium stearate" ('587 Patent, Claim 7; '632 Patent, Claim 15) | 5.5-6.4 mg of magnesium stearate |

## IV. CONSTRUCTION OF DISPUTED TERMS

### 1. "single dose administration" ('587 Patent, Claims 1, 5, and 7)

a. *Plaintiffs' proposed construction*: "administration all at one time"

b. *Defendants' proposed construction*: "once daily administration"

c. *Court's construction*: "administration all at one time"

Plaintiffs argue that their proposed construction of "single dose administration" is the ordinary and customary meaning of the term. (D.I. 129 at 6). Plaintiffs cite to medical dictionaries to support their contention that the ordinary meaning of dose in the pharmaceutical arena is the "amount of a pharmaceutical composition to be administered at one time." (*Id.*). Plaintiffs also argue that their proposed construction is supported by the intrinsic evidence, as the specification does not use dose, but uses different language, such as "daily dose" or "per day" to refer to the overall amount of the compound to be administered throughout a daily period. (*Id.* at

7). Plaintiffs further assert that Defendants' proposed construction would violate multiple rules of claim construction as it would limit the claims to one embodiment in the specification, exclude a preferred embodiment from the claims, and exclude Plaintiffs' VIBERZI product from the claims. (*Id.* at 9).

Defendants argue that a person having ordinary skill in the art (PHOSITA) would have understood the disputed term to mean "once daily administration" based on the claim language and patent specification. (*Id.* at 11). Defendants contend that the specification supports their proposed construction, as it never defines "single dose administration," but instead discloses a variety of dosing regimens. (*Id.* at 12). Defendants argue that when the specification does discuss single doses, it states that "dosage formulations of the present disclosure may be administered in a single daily dose or the total daily dosage may be administered in divided doses of two, three or four times daily." (*Id.* (quoting '587 patent at 14:29-32)). Further, Defendants note that the specification describes only a daily dose when it discloses achievement of clinical outcomes. (*Id.*). Based on this language, Defendants assert that a PHOSITA would have understood the disputed term to mean "once daily administration." (*Id.*). Defendants also argue that Plaintiffs' proposed construction ignores the term "administration" and does not provide any separate meaning to "single." (*Id.* at 13).

The specification uses "single dose administration" one time, stating that a "specific embodiment is an abuse deterrent mono-phasic pharmaceutical composition suitable for single dose administration." (D.I. 1-1, Exh. D at col. 5:14-15). This is the same language used in the claims. (*Id.* at cols. 33:62-62; 34:64-65; 35:19-20, 41-42; 36: 17-18). The specification does not otherwise define "single dose administration," but describes "between two administrations per day and eight administrations per day," "between two administrations per day and four

administrations per day," and refers to "daily dose," "single daily dose," and "total daily dose." (*Id.* at cols. 5:64-65; 6:9-10; 14:1, 30, 38). The use of "daily" and "per day" to modify "dose" and "administration" indicates that the patentees specified where there was a certain interval of time for a dose or administration. The term "daily" is not used in the claims. (*See id.* at col. 33-36).

The extrinsic evidence supports Plaintiffs' construction of the term. *Oxford Concise Medical Dictionary* describes dose as "a carefully measured quantity of a drug that is prescribed by a doctor to be given to a patient at any one time." (D.I. 130, Exh. G at 221). *Merriam-Webster's Medical Dictionary* states that dose is "the measured quantity of a therapeutic agent to be taken at one time." (*Id.*, Exh. H at 186). Similarly, *Dorland's Illustrated Medical Dictionary* lists dose as "a quantity of an agent to be administered at one time, such as a specified amount of medication." (*Id.*, Exh. I at 564). The American Medical Association's *Manual of Style* describes dose as "the quantity to be administered at one time, or the total quantity administered during a specified period." (D.I. 130-1, Exh. U at 392). In this case, there is no "specified period" described in the claims, so the definition of "the quantity to be administered at one time" applies.

Based on the extrinsic evidence, the plain and ordinary meaning of "dose," which a PHOSITA would have understood, "single dose" is the amount of a pharmaceutical agent to be taken at one time. There is a difference between "single dose" and "daily dose." *Pharmaceutical Calculations*, 13th Edition, distinguishes the two stating, "The dose of a drug is the quantitative amount administered or taken by a patient for the intended medicinal effect. The dose may be expressed as a single dose, the amount taken at one time; a daily dose; or a total dose, the amount taken during the course of therapy." (*Id.*, Exh. R at 103). A PHOSITA would not construe

"single dose" to mean "once daily," as "single dose" and "daily dose" are different terms with different meanings.

Further, adopting Defendants' proposed construction would exclude the twice-daily preferred embodiment described in the specification. The specification describes administering the present disclosure twice daily between certain time intervals, and states, "In these preferred embodiments, the total daily dose is administered twice daily." (D.I. 1-1, Exh. D at col. 14:37-39). Defendants' proposed construction of "once daily administration" would read out the preferred embodiment described in the specification, as such embodiment describes twice daily administration. "[A] claim construction that excludes the preferred embodiment is highly disfavored," *Duncan Parking Techs. v. IPS Grp.*, 914 F.3d 1347, 1364 (Fed. Cir. 2019), and such a construction "is rarely, if ever, correct." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1583 (Fed. Cir. 1996). Under Federal Circuit precedent, Defendants' proposed construction is highly disfavored as it excludes a preferred embodiment.

The Court adopts Plaintiffs' proposed construction of the disputed term as it reflects the plain and ordinary meaning of "single dose administration."

**2. "silicified microcrystalline cellulose"**

a. *Plaintiffs' proposed construction*: "a mixture of microcrystalline cellulose and colloidal silicon dioxide"

b. *Defendants' proposed construction*: "a co-dried or co-sprayed combination of only microcrystalline cellulose (98%) and colloidal silicon dioxide (2%)"

c. *Court's construction*: "a coprocessed combination of microcrystalline cellulose (98%) and colloidal silicon dioxide (2%)"

The parties dispute whether there is a specific method of creation for silicified microcrystalline cellulose and whether silicified microcrystalline cellulose has a specific ratio of microcrystalline cellulose to colloidal silicon dioxide. "[A] skilled artisan reads a claim term not

only in the context of the claim at issue, but also in the context of the entire patent, including the written description and prosecution history, as well as relevant extrinsic evidence." *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1320-21 (Fed. Cir. 2016).

The specification refers to "silicified microcrystalline cellulose (USP Silicified Microcrystalline Cellulose; intimately associated microcrystalline cellulose and colloidal silicon dioxide particles; in a preferred example, high density silicified microcrystalline cellulose 'HD-90')." (D.I. 1-1, Exh. D at col. 11:6-11). In turn, the United States Pharmacopoeia (USP) states, "Silicified Microcrystalline Cellulose is composed of intimately associated microcrystalline cellulose and colloidal silicon dioxide particles, derived from aqueous coprocessing prior to drying the material during manufacture." (D.I. 131, Exh. II at 1951).

The parties dispute whether silicified microcrystalline cellulose is a "mixture" or a "co-dried or co-sprayed combination" of microcrystalline cellulose and colloidal silicon dioxide. (D.I. 129 at 29-30, 34-35). The Court resolves this dispute by construing silicified microcrystalline cellulose to be a "coprocessed combination." The specification refers to the USP in defining silicified microcrystalline cellulose, and the USP states that silicified microcrystalline cellulose is "derived from aqueous coprocessing prior to drying the material during manufacture." (D.I. 131, Exh. II at 1951). Therefore, construing silicified microcrystalline cellulose to be "coprocessed" is supported by the specification.

Further, this construction is supported by the parties' experts and extrinsic evidence. In their argument, Plaintiffs refer to the *Handbook of Pharmaceutical Excipients*. (D.I. 129 at 25.). The *Handbook* states, "Silicified microcrystalline cellulose is manufactured by co-drying a suspension of microcrystalline cellulose particles and colloidal silicon dioxide such that the dried finished product contains 2% w/w colloidal silicon dioxide." (D.I. 130, Exh. L at 151). As

confirmed by both parties' experts, "co-drying" is a type of coprocessing. (*Id.*, Buckton Decl. at 15; Sinko Decl. at 22-24). Further, in his report, Plaintiffs' expert, Dr. Sinko, discusses extrinsic evidence that states that silicified microcrystalline cellulose is coprocessed. (D.I. 130, Sinko Decl. at 22-23). Dr. Sinko also cites to U.S. Patent No. 5,585,115, which explains, "It is most preferred in the present invention that the microcrystalline cellulose and silicon dioxide are coprocessed, resulting in an intimate association of these ingredients." (*Id.* at 23 (citing D.I. 130, Exh. N at 10:4-7)). Similarly, Defendants' expert, Dr. Buckton, discusses extrinsic evidence describing silicified microcrystalline cellulose as being coprocessed. (*Id.*, Buckton Decl. at 14-16). Dr. Buckton also states that the "language in Defendants' proposed construction 'a co-dried or co-sprayed combination' is a reference to the customary manner in which MCC and CSD are 'co-processed' together." (*Id.* at 15). Both Plaintiffs and Defendants, and their experts, cite extrinsic evidence that states that silicified microcrystalline cellulose is coprocessed. This evidence, in conjunction with the specification, leads the Court to conclude that silicified microcrystalline cellulose is a "coprocessed combination."[1]

The parties also dispute the ratios of microcrystalline cellulose and colloidal silicon dioxide in silicified microcrystalline cellulose. Plaintiffs argue that their proposed construction is the ordinary and customary meaning of the term. (D.I. 129 at 24). Plaintiffs contend that their construction is supported by the *Handbook of Pharmaceutical Excipients*, which describes silicified microcrystalline cellulose as "a synergistic, intimate physical mixture of two components: microcrystalline cellulose and colloidal silicon dioxide." (*Id.* at 25 (citing D.I. 130,

[1] I am not importing a manufacturing limitation into the claim (D.I. 129 at 35) or making this a "product-by-process" term. Rather, silicified microcrystalline cellulose has properties such as the intimate association that arise from the coprocessing, and are not captured by describing it merely as a mixture or combination.

Exh. L at 149)). Plaintiffs also argue that on the priority date for the '587 and '632 patents, silicified microcrystalline cellulose existed in other ratios than the 98:2 ratio proposed by Defendants. (*Id.*). Plaintiffs cite the article *Co-Processed Excipients: A Patent Review* which notes that silicified microcrystalline cellulose exists in a "Most Preferred Ratio" where "colloidal silicon dioxide comprises from about 1.25% to about 5% by weight relative to MCC [microcrystalline cellulose]." (*Id.* (citing D.I. 130, Exh. M at 79)). Plaintiffs also cite to another patent referring to silicified microcrystalline cellulose in ratios containing up to 20% by weight colloidal silicon dioxide. (*Id.* (citing D.I. 130, Exh. N at 5:1-11)).

Defendants argue that the 98:2 ratio for microcrystalline cellulose and colloidal silicon dioxide is the customary meaning of silicified microcrystalline cellulose. (*Id.* at 26). Defendants support their argument with numerous citations to academic pharmaceutical references. (*Id.* (citing D.I. 131, Exh. 32 at 953; Exh. 33 at 99; Exh. 34 at 100; Exh. 35 at 77; Exh. 36 at 100)). Each of these references describes silicified microcrystalline cellulose as having a ratio of 98% microcrystalline cellulose to 2% colloidal silicon dioxide. For instance, *Case studies with new excipients: development, implementation and regulatory approval* states that silicified microcrystalline cellulose "is a coprocessed excipient that combines 98% microcrystalline cellulose (MCC) and 2% fumed colloidal silicon dioxide." (D.I. 131, Exh. 32 at 953). The other cited references make nearly identical statements. (*See id.*, Exh. 33 at 99; Exh. 34 at 100; Exh. 35 at 77; Exh. 36 at 100).

The weight of the relevant extrinsic evidence leads the Court to conclude that a PHOSITA would understand silicified microcrystalline cellulose to contain a 98:2 ratio of microcrystalline cellulose to colloidal silicon dioxide. The *Handbook of Pharmaceutical Excipients* states, "Silicified microcrystalline cellulose is a synergistic, intimate physical mixture

of two components: microcrystalline cellulose and colloidal silicon dioxide. . . . Silicified microcrystalline cellulose contains 2% w/w colloidal silicon dioxide." (D.I. 130, Exh. L at 149). While Plaintiffs cited the first sentence, the second sentence specifies that silicified microcrystalline cellulose has a 98:2 ratio of microcrystalline cellulose to colloidal silicon dioxide. Further, the *Handbook* refers to *ProSolv* as a synonym of "silicified microcrystalline cellulose." (*Id.*). ProSolv was the only commercially available silicified microcrystalline cellulose at the relevant date of the patent. (*Compare id. with* D.I. 130, Exh. O at 16-17 (referring to ProSolv as the commercially available ingredient)). Dr. Buckton also stated that a PHOSITA "would have known of, and understood the meaning of, SMCC in relation to the excipient on the market in 2013 which had that name" in reference to ProSolv. (D.I. 130, Buckton Decl. at 8).

Since the expiration of the patent on silicified microcrystalline cellulose, other products have entered the market, but Dr. Buckton states that he is "only aware of this excipient being marketed and sold as the 98:2 ratio." (*Id.*). He also reported that to his knowledge, "USP silicified microcrystalline cellulose has always contained the 98:2 ratio of constituents" and that he is "aware of no other grade of commercially available silicified microcrystalline cellulose that does not utilise this 98:2 ratio." (*Id.* at 17).

Both parties' experts opine on whether the ordinary and customary meaning of silicified microcrystalline cellulose would contain a 98:2 ratio of microcrystalline cellulose to colloidal silicon dioxide. However, the Court finds Dr. Buckton's report to be more persuasive. Dr. Buckton cites a myriad of extrinsic evidence supporting Defendants' contention that a PHOSITA would have known silicified microcrystalline cellulose to be made of 98% microcrystalline cellulose and 2% colloidal silicon dioxide. (*Id.* at 8-12). Further, Dr. Buckton distinguishes the

evidence cited by Plaintiffs' expert, noting that those sources do not even use the term silicified microcrystalline cellulose. (*Id.* at 14).

The weight of the extrinsic evidence,[2] including the *Handbook of Pharmaceutical Excipients*, the commercial availability of silicified microcrystalline cellulose in the 98:2 ratio, and the parties' expert reports, shows that a PHOSITA would have understood silicified microcrystalline cellulose to be 98% microcrystalline cellulose and 2% colloidal silicon dioxide.

Based on the evidence presented and the parties' arguments, the Court, therefore, construes "silicified microcrystalline cellulose" to mean "a coprocessed combination of microcrystalline cellulose (98%) and colloidal silicon dioxide (2%)."

**3. "colloidal silica" / "colloidal silicon dioxide"**

a. *Plaintiffs' proposed construction*: plain meaning or "submicroscopic fumed silicon dioxide"

b. *Defendants' proposed construction*: "an amount of [colloidal silica/colloidal silicon dioxide] separate from the amount of colloidal silicon dioxide present in the silicified microcrystalline cellulose"

c. *Court's construction*: "an amount of [colloidal silica/colloidal silicon dioxide] distinct from the amount of colloidal silicon dioxide present in the silicified microcrystalline cellulose"

At the heart of this dispute are Defendants' efforts to distinguish the colloidal silicon dioxide present in the compound from the colloidal silicon dioxide that interacts with the microcrystalline cellulose to create silicified microcrystalline cellulose. (*See* D.I. 136 at 89:12-16). Plaintiffs argue that this term should have its plain and ordinary meaning or their proposed construction, as Defendants' proposal is a "litigation-driven construction" of the term. (D.I. 129 at 39-40). Plaintiffs further contend that Defendants' proposed construction is claim application,

[2] I rely upon extrinsic evidence because the intrinsic evidence, while not supporting any ratio other than 98:2, also does not foreclose some other ratio.

not claim construction, and is premature. (*Id.* at 49). Defendants, meanwhile, argue that their construction of the term is supported by the claim language and the specification, as both list the two elements separately and the specification describes their different functions. (*Id.* at 42-44).

At oral argument, however, the parties agreed to the Court's proposed construction. (D.I. 136 at 88:6-11, 88:25-89:1). While Plaintiffs maintained the view that such construction is claim application, they agreed that they could "get there" and that "distinct is better than" what the Defendants' proposed. (*Id.* at 87:16-88:16). Defendants concurred, stating that "distinct from would be fine as long as it's clear that the [colloidal silicon dioxide] in the silicified microcrystalline cellulose cannot count." (*Id.* at 88:25-89:1). Therefore, the Court adopts the consented-to construction.

**4. "about 0.55%-0.95% by weight of [colloidal silica/colloidal silicon dioxide]"**

a. *Plaintiffs' proposed construction*: "0.50-1.00% by weight of [colloidal silica/colloidal silicon dioxide]

b. *Defendants' proposed construction*: "0.50-0.98% by weight of [colloidal silica/colloidal silicon dioxide]

c. *Court's construction*: "0.50-1.00% by weight of [colloidal silica/colloidal silicon dioxide]

**5. "about 0.55%-0.95% by weight of magnesium stearate"**

a. *Plaintiffs' proposed construction*: "0.50-1.00% by weight of magnesium stearate"

b. *Defendants' proposed construction*: "0.50-0.98% by weight of magnesium stearate"

c. *Court's construction*: 0.50-1.00% by weight of magnesium stearate

As both disputed terms concern the construction of "about 0.55%-0.95%," the terms will be construed to have the same meaning. The parties agree that the claimed range extends beyond "0.55-0.95%" and that the lower bound of the range should by 0.50%. (D.I. 129 at 53). The area of dispute is the upper bound of the range. Plaintiffs argue that the upper bound should be 1.00%

as this value is halfway between 1.04% (the upper range of what would be rounded to 1.0%) and 0.95%. (*Id.* at 54). Plaintiffs also contend that this range is symmetrical with the lower bound, which is 0.05% less than the value in the claim. (*Id.*). Defendants argue that the upper bound of the range should be 0.98%, as that is halfway to the matching endpoint of the next broadest range. (*Id.* at 55-56). Defendants contend that "about" does not expand the range symmetrically because moving from range 3 to range 4, the ends of the ranges are not expanded symmetrically, as the lower end of the range is expanded by 0.10 and the upper end of the range is expanded by 0.05. (*Id.* at 57).

Under Federal Circuit precedent, "[a] word or phrase used consistently throughout a claim should be interpreted consistently." *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998). The parties agree that "about" expands the lower end of the range by 0.05. As "about" is to be interpreted consistently throughout the claims, it also expands the upper end of the range by 0.05, to 1.00. Therefore, the Court construes "about 0.55%-0.95% by weight" to mean "0.50-1.00% by weight" for both terms in dispute.[3]

[3] I note that it is not clear that the dispute on these terms has any impact on the case. (D.I. 136 at 71:16-19; 76:5-77:8).